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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/048,966 03/26/98 SHANMUGASUNDARAM E 53000/1001

EXAMINER

HM12/0113

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LILLING, H

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 01/13/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on DECEMBER 21, 1998

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-24 is/are pending in the application.
Of the above, claim(s) 1-13, 20, 22, 24 is/are withdrawn from consideration.
☐ Claim(s) is/are allowed.
☒ Claim(s) 14-15-16-17-18-19, 21, 23 is/are rejected.
☐ Claim(s) is/are objected to.
☒ Claim(s) 1-24 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number)
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received:

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4 (4000000)
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

Ser No 09/048,966

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit: 1651

1. Receipt is acknowledged of the election, information prior art disclosure statement and amendment filed December 21, 1998.

2. Claims 1-24 remain present in the instant application.

3. Applicant has elected Invention III, Claims 14-19, 21 or 23 , drawn to a method of administering the composition for treating diabetic patients, impaired glucose tolerance , regenerating the pancreatic islets , increasing endogenous insulin levels in a patient or proinsulin in a patient, classified in class 514, subclass one plus.

Claims 1-13 , drawn to a method for isolating a composition from the leaves of *Gymnema sylvestre* a composition obtained from the leaves of *Gymnema sylvestre*, classified in class 424, subclass 195.1 as well as claims 20, 22 and 24 have been withdrawn from consideration.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1651

Claims 14 - 17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hiji U.S. 4,912,089 or Claims 14 and 117-19 and 21 over Shanmugasundaram et al (AR).

teaches that the dried leaf extracts of GS prepared by essentially the same procedure as required by the instant claims were able to increase the beta and islets cells, see Examples page 268.

The reference to Hiji teaches the preparation of extracts which are within the scope of the claimed extract, see column 2 whereby the *Gymnema sylvestre* is prepared by immersing dried leaves in an aqueous solution with alcohol (see line 33) whereby the solution is adjusted to a pH of 3 and then washed with water to yield a precipitate that is considered to be the same or functions as the same as that required by the instant claims absence a showing to the contrary.

The reference also teaches that a patient is treated with the extract, see Figure 3, whereby the blood sugar is decreased or inhibited which disclosure is considered to be the same as that claimed for the treatment of diabetic patient or for a glucose tolerance test, see column 7, lines 47-50.

Shanmugasundaram et al (AR) teaches that the dried leaf extracts of GS prepared by essentially the same procedure as required by the instant claims were able to increase the beta and islets cells, see Examples page 268.

Art Unit: 1651

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-19, 21 or 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiji U.S. 4,912,089 alone for Claims 14-17 or Shanmugasundaram et al (AR) further in view of Womack, U.S. 5,730,98 for Claims 14-19, 21 or 23 .

Hiji teaches the preparation of extracts which extracts are useful for controlling sugars as in oral glucose tolerance tests and inhibiting the increase in sugar concentrations in blood sugars.

Womack teaches that GS extracts have reasonable expectations to enhance endogenous insulin, regenerate beta cells, reduce blood sugar and treat diabetics.

Shanmugasundaram et al (AR) teaches that the dried leaf extracts of GS prepared by essentially the same procedure as required by the instant claims were able to increase the beta and islets cells, see Examples page 268.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.


Art Unit: 1651

Thus, in view of the combination of references, one of ordinary skill in the art would have considered at the time the invention was made that the references strongly suggested and motivated one in the art to employ the extract of Hiji or Shanmugasundaram et al (AR) which two references teach that the dried leaf extracts of GS prepared by essentially the same procedure as required by the instant claims were able to increase the beta and islets cells, control or treat the various ailments of Claims 14-19, 21 and 23, absent a showing of unexpected or unobvious process steps or data on the record. The specification examples and data do not appear to demonstrate unexpected results based on the disclosures of the prior art which would have expected the improved results.

6. **No claim is allowed.**

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is (703) 308-2034 and fax number (Art Unit 1651) is (703) 305-7939 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL
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Art Unit **1651**
January 12, 1999


HERBERT J. LILLING
PATENT EXAMINER
GROUP 100 ART UNIT 1651